Clinical and Statistical Evaluation of 1st Automatic: A Pilot Study

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The patient’s problem

- Patients with respiratory disease are at risk of inadequate lung ventilation and inadequate tissue oxygenation.
- Patients with metabolic diseases are at risk of acid-base abnormalities.
- An **arterial blood gas analysis** is a simple procedure that can be performed bedside and can provide information about:
  - lung ventilation,
  - tissue oxygenation and
  - acid-base status.
The clinician’s problem

- Medical personnel at the ICU are under considerable stress in their everyday clinical settings and therefore prone to make errors
- 75% of all laboratory medical errors occur during the pre-analytical phase
- An error in the pre-analytical phase of an arterial blood gas analysis can seriously influence the diagnosis and treatment
• Common pre-analytical errors
  – Wrong patient identification
  – Air bubbles in the specimen
  – Insufficient mixing prior to analysis
Partial automation developed by Radiometer

- A partially automated bar code scanning system minimizes the risk of patient ID and specimen mix up significantly.
- Automatic mixing of the specimen ensures a consistently homogeneous specimen prior to analysis.
SafePICO

- Needle cover
- Pre-heparinised syringe
- Integrated metal ball
- SafeTIPCAP
- Unique barcode

Kilde: www.radiometer.com/1st
1. Scanning
2. Identification
3. Mixing
4. Analysing
Objective of the study

• To assess whether 1st Automatic is a suitable alternative to the conventional method
• To examine whether there is a difference between the two methods
Patients and Specimens

• Department of Anaesthesia and Intensive Care, Aalborg Hospital
• 5 patients randomly selected
• 21 pairs of specimens
  – one specimen processed by the conventional method and
  – one specimen processed by 1st Automatic
• The nurse collected both specimens
• Both specimens in a pair was analyzed by the same analyzer (ABL825 / ABL837)
  – One of the specimens in each pair was processed by the mounted FLEXQ module (performed by the observer)
  – the other specimen was processed manually (performed by the nurse)
• Nine parameters: pH, pCO2, pO2, cNa+, cK+, cCa2+, cGlu, cLac and tHb.
Comparison of Procedures

- Bland-Altman plots
  - depict the difference in the blood gas parameters for each pair of specimens (conventional method – 1st Automatic) as a function of the mean of the two specimens in a pair

- Paired-sample t-tests

- A mean difference of 10%, or less, of the normal range for each parameter was considered to be clinically insignificant
• 21 paired samples from five patients. The table shows the p-values of the T tests. The blood gas pressures (pXX) are in kPa and the blood concentrations (cXX) in mmol/.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Normal range</th>
<th>Data range</th>
<th>Mean (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M/F</td>
<td>F</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>7.35 - 7.45</td>
<td>7.342 - 7.471</td>
<td>-0.0012 (-0.0026, 0.0002)</td>
<td>0.082</td>
</tr>
<tr>
<td>pCO₂</td>
<td>4.67 - 6.40</td>
<td>4.27 - 6.00</td>
<td>4.24 - 6.57</td>
<td>0.324 (-0.0156, 0.0803)</td>
</tr>
<tr>
<td>pO₂</td>
<td>11.07 - 14.40</td>
<td>7.5 - 22</td>
<td>0.0110 (-0.2898, 0.3117)</td>
<td>0.940</td>
</tr>
<tr>
<td>cNa⁺</td>
<td>136 - 146</td>
<td>132 - 140</td>
<td>0.7143 (0.2127, 1.2159)</td>
<td>0.008</td>
</tr>
<tr>
<td>cK⁺</td>
<td>3.4 - 4.5</td>
<td>3.4 - 5.4</td>
<td>0.0048 (-0.0346, 0.0442)</td>
<td>0.803</td>
</tr>
<tr>
<td>cCa²⁺</td>
<td>1.15 - 1.29</td>
<td>1.01 - 1.23</td>
<td>0.0152 (0.0065, 0.0240)</td>
<td>0.002</td>
</tr>
<tr>
<td>cGlu</td>
<td>3.89 - 5.83</td>
<td>5.6 - 11.5</td>
<td>0.0905 (-0.0060, 0.1869)</td>
<td>0.065</td>
</tr>
<tr>
<td>cLac</td>
<td>0.5 - 1.6</td>
<td>0.5 - 2.2</td>
<td>0.0286 (-0.0216, 0.0787)</td>
<td>0.249</td>
</tr>
<tr>
<td>ctHb</td>
<td>8.4 - 10.9</td>
<td>7.4 - 9.9</td>
<td>5.0 - 8.2</td>
<td>-0.0286 (-0.0496, -0.0075)</td>
</tr>
</tbody>
</table>
Discussion

- pH
  - t-test gives $p = 0.082$, which indicates that there might be a bias
  - However, the mean difference is around 1% of the normal range

- pCO2 and pO2
  - t-test shows $p = 0.17$ for pCO2, and $p = 0.94$ for pO2, which indicates that no bias
  - Mean difference is less than 2% and 1% respectively
• cNa+
  – t-test shows $p = 0.008$, which is statistically significant
  – The mean difference is $0.714$, which is $7\%$ of the normal range

• cK+
  – t-test shows $p = 0.80$
  – Mean difference of less than $1\%$, which indicates that no bias is present
• cCa2+ and ctHb
  – t-test shows p = 0.002 for cCa2+ and p = 0.010 for ctHb
  – the difference being 10% and 1% respectively

• cGlu and cLac
  – t-test shows p = 0.065 for cGlu and p = 0.25 for cLac
  – The difference is 5% and 3% respectively
Summary

- There was a good consistency between the results using 1st Automatic and the conventional method.
- It was not possible to show any clinically significant difference between the two procedures.
- The consequences on workflow using the two procedures have not been addressed in the present study.
- 1st Automatic is now being used at the hospital.
• The FLEXQ, safePICO and 1st Automatic clients were provided by Radiometer Denmark

• Thanks for their help
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